

DSJ1&2-PR Exh 567

RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE
LITIGATION

This document relates to:

*Track One Cases*¹

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

WALMART INC.'S RESPONSES TO
PLAINTIFFS (FIRST) COMBINED DISCOVERY REQUESTS
TO NATIONAL RETAIL PHARMACIES DEFENDANTS

Pursuant to Federal Rules of Civil Procedure 26, 33, and 34, Defendant Walmart Inc. (“Walmart”) hereby responds to Plaintiffs [sic] (First) Combined Discovery Requests to National Retail Pharmacies Defendants (“Combined Requests”).

PRELIMINARY STATEMENT

Walmart incorporates its General Objections asserted in Walmart Inc.’s Amended and Supplemental Objections and Responses to Plaintiffs’ Requests for Production and First Set of Interrogatories, including but not limited to its objections to the term “suspicious order” as vague and ambiguous. All responses are subject to and without waiving Walmart’s objections.

Walmart further objects to these Combined Requests on the grounds that they exceed the number of written discovery requests permitted as to Walmart pursuant to Case Management Order No. 1 and based on the procedural history outlined in various communications with the plaintiffs

¹Pursuant to Case Management Order One (“CMO-1”) (Dkt. No. 232), discovery is authorized only in the following three cases: *The County of Cuyahoga, Ohio v. Purdue Pharma L.P., et al.*, Case No. 17-OP-45004 (N.D. Ohio); *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-OP-45090 (N.D. Ohio); and *The City of Cleveland, Ohio, v. AmerisourceBergen Drug Corp., et al.*, Case No. 18-OP-45132 (N.D. Ohio) (“Track One Cases”). Accordingly, these objections and responses relate only to the Track One Cases, and not to any other case currently in, or that may be added to, MDL No. 2804 in the Northern District of Ohio (“MDL”).

**RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER**

and Special Master. In particular, Walmart objects to Plaintiffs (1) raising the issue of responses to the Combined Requests with the Court on November 20 without notice to the pharmacies of their intention to do so and without giving the Court the benefit of relevant procedural history or correspondence, and (2) taking a position inconsistent with their prior representations that the Combined Requests did not require separate responses.

Walmart objects to these Combined Requests to the extent that they seek information inconsistent with the Court's and Special Master's rulings regarding scope of discovery. Consistent with Discovery Ruling No. 3, Walmart will respond with information relevant to Walmart's distribution of the Schedule II opioids listed in Appendix A ("Relevant CII Opioids") to Cuyahoga County, Ohio and Summit County, Ohio ("Relevant Geographic Area") during the period from January 1, 2006 to April 25, 2018 ("Relevant Time Period"). Walmart only distributed the Relevant CII Opioids to its own pharmacies and ceased distribution of all Schedule II Controlled Substances in April 2018.

Walmart incorporates the responses in Walmart Inc.'s Amended and Supplemental Objections and Responses to Plaintiffs' Requests for Production and First Set of Interrogatories. Walmart reserves the right to amend and/or supplement these responses. Discovery is ongoing, the close of fact discovery is set for January 25, 2019, and testimony regarding Walmart's order monitoring activities is being elicited during depositions of fact witnesses and has been expressly sought by Plaintiffs in their Rule 30(b)(6) Notice (deposition scheduled). (*See, e.g.,* Topics (a) Your past/present suspicious orders monitoring system, SOMS program, policies and procedures; and (j) How Your policy, procedures, standards and metrics used to identify suspicious orders has [sic] changed over time).

**RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER**

SPECIFIC OBJECTIONS AND RESPONSES

2. Please produce each of your *Suspicious Order Monitoring System (SOMS)* policies and procedures since January 1, 2006 and identify the Bates stamp range for each; please identify the effective date(s) each was in force and effect.

RESPONSE:

Walmart objects to Combined Request No. 2 on the grounds that it is vague and ambiguous as to the meaning of the undefined terms “policies,” “procedures,” and “Suspicious Order Monitoring System (SOMS).”

Subject to and without waiving its specific and General Objections, Walmart states that during the Relevant Time Period it had in place numerous written and unwritten policies and procedures to monitor orders from its pharmacies and prevent diversion. Walmart, however, interprets this request to seek the production and identification of Walmart’s written policies and procedures specific to suspicious order monitoring of the Relevant CII Opioids. Pursuant to that interpretation, Walmart states that it has already produced such written policies and procedures. Their Bates numbers and approximate effective dates are as follows:

Document	Approximate Effective Dates
WMT_MDL_000011106	11/2010 – 10/2014
WMT_MDL_000011107-11109	10/2014 – 3/2015
WMT_MDL_000000963-965	3/2015 – 12/2015
WMT_MDL_000000966-968	12/2015 – 6/2017
WMT_MDL_000000969-971	6/2017 – 11/2017
WMT_MDL_000008377-8379	8/2014 – 1/2015
WMT_MDL_000004237-4239	1/2015 – 4/2017
WMT_MDL_000004781-4783	4/2017 – 11/2017

Out of an abundance of caution in light of the Court’s November 21, 2018 order, Walmart further states that in addition to the written policies and procedures reflected in the documents

**RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER**

cited above, Walmart employed additional policies, practices and procedures to monitor orders from its pharmacies during the Relevant Time Period including:

- From as early as 1994 until 2010, employees in Walmart's pharmacy distribution centers reviewed Controlled Drug Stock Exception Reports, followed up on orders by speaking with pharmacists, and escalated issues to market and/or region leadership as needed to investigate orders and/or resolve concerns.
- From approximately 2004 until at least August 2010, consistent with direction from DEA, employees in Walmart's Schedule II distribution center, Distribution Center No. 6045 ("DC 6045"), faxed monthly reports to the Little Rock DEA office based on their review of Controlled Drug Stock Exception Reports. (*See, e.g.*, WMT_MDL_000044441).
- From approximately 2010 until approximately 2015, employees in Walmart's pharmacy distribution centers reviewed Controlled Drug Stock Exception Reports and internally circulated reports listing all stores/items above 4% for further review and follow-up as needed.
- From approximately 2011 until approximately 2015, Walmart implemented order alerts in Reddwerks (Walmart's order fulfillment system) that flagged orders for controlled substances of 50 bottles or more and orders for amounts 30% higher than a rolling 4 week average for that item.
- From approximately July 2012 until approximately 2015, employees in Walmart's DC 6045 implemented a hard limit of 20 bottles for shipments of Oxycodone 30 mg, and internally circulated a report listing orders for Schedule II controlled substances of more than 20 bottles for further review and follow-up as needed. (*See, e.g.*, WMT_MDL_000009423 and the deposition of Jeff Abernathy).
- From approximately 2015 through November 2017, Walmart implemented enhanced thresholds in Reddwerks and a tiered review process (involving teams from Walmart's Health & Wellness Logistics and Practice Compliance divisions) for orders placed by its pharmacies. (*See, e.g.*, depositions of Jeff Abernathy and Chad Ducote).
- From November 2017 until the end of the Relevant Time Period when Walmart ceased all distribution of Controlled Substances, Walmart used the Buzzeo system to analyze orders from Walmart pharmacies and flag Orders of Interest, which were reviewed by Walmart's Health & Wellness Practice Compliance personnel. All Orders of Interest identified using the Buzzeo system were reported to DEA. (*See, e.g.*, WMT_MDL_000053813).
- For the entire Relevant Time Period, employees in Walmart's pharmacy distribution centers monitored orders. (*See, e.g.*, processes described during the deposition of Jeff Abernathy).

**RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER**

- For the entire Relevant Time Period, Walmart cooperated fully in DEA audits, which included review of Walmart's order monitoring processes.

Further in response to Combined Request No. 2, pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, Walmart refers plaintiffs to the documents produced in response to plaintiffs' written discovery requests and to the testimony provided by Jeff Abernathy and Chad Ducote during their depositions in this case. In addition, testimony regarding Walmart's order monitoring activities will be elicited during depositions of additional fact witnesses (8 additional fact witness depositions have been scheduled). Finally, Walmart has agreed to provide corporate testimony concerning Walmart's policies and procedures for suspicious orders and orders of interest with respect to Walmart's distribution of the Relevant CII Opioids in response to Plaintiffs' Rule 30(b)(6) Notice (deposition scheduled). (*See, e.g.,* Topics (a) Your past/present suspicious orders monitoring system, SOMS program, policies and procedures; and (j) How Your policy, procedures, standards and metrics used to identify suspicious orders has [sic] changed over time).

The following requests will be addressed collectively:

3. Please identify and describe each *suspicious order* your Suspicious Order Monitoring System (SOMS) identified since January 1, 2006 and produce all documents related thereto; please identify the Bates stamp range for each related to *Case Track One*.
4. Please identify each suspicious order you *reported* to the DEA since January 1, 1996 and produce all documents related thereto; please identify the Bates stamp range for each related to *Case Track One*.
5. For each suspicious order you identified but did not report to the DEA since January 1, 2006, please describe in as much detail as possible the reasons and produce all documents related thereto; please identify the Bates stamp range for each related to *Case Track One*.
6. For each suspicious order you reported to the DEA since January 1, 2006, please identify whether you *declined* the order or *shipped* the order and produce all documents related thereto; please identify the Bates stamp range for each related to *Case Track One*.
7. For each suspicious order you reported and then shipped since January 1, 2006, please produce all documents related to your "*due diligence*" for each; please identify the Bates stamp range for each related to *Case Track One*.

RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER

RESPONSE:

Subject to and without waiving any of its Objections, Walmart states that Walmart did not identify any suspicious order for the Relevant CII Opioids from a pharmacy in the Relevant Geographic Area during the Relevant Time Period. Accordingly, Walmart did not ship any suspicious order into the Relevant Geographic Area during the Relevant Time Period.

Dated: November 30, 2018

s/ Tara A. Fumerton

Tina M. Tabacchi

Tara A. Fumerton

JONES DAY

77 West Wacker Drive

Chicago, Illinois 60601

Telephone: (312) 782-3939

Email: tmtabacchi@jonesday.com

tfumerton@jonesday.com

Counsel for Walmart Inc.

RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER

Appendix A – Relevant Schedule II Opioid Drug List

- alfentanil
- codeine
- dihydrocodeine
- diphenoxylate
- fentanyl
- hydrocodone
- hydromorphone
- levorphanol
- meperidine
- methadone
- morphine
- opium
- oxycodone
- oxymorphone
- remifentanyl
- sufentanil
- tapentadol

**RESPONSES CONTAIN WALMART CONFIDENTIAL
INFORMATION SUBJECT TO PROTECTIVE ORDER**

CERTIFICATE OF SERVICE

I hereby certify that, this 30th day of November, 2018, I caused the foregoing to be served via electronic mail on counsel of record for plaintiffs in this case via mdl2804discovery@motleyrice.com, as well as Michael Innes (MInnes@carellabyrne.com) and Zachary Bower (ZBower@carellabyrne.com).

/s/ Kelly M. Bonovich

Kelly M. Bonovich

Counsel for Walmart Inc.

NAI-1504049008

WMT_MDL_000000963 - WMT_MDL_000000965

21-0402

Pharmacy Manual

Evaluating Orders of Interest and Suspicious Order Reporting



Purpose

DEA, VAWD, and other regulatory agencies require distributors of pharmaceutical products and medical devices to have a system in place designed to identify and report suspicious orders. The following procedure will be followed by Walmart to evaluate Orders of Interest and to report Suspicious Orders to the appropriate federal and state agencies.

Procedures

Definitions

Order of Interest – An order that warrants follow-up evaluation to determine whether it is suspicious. Orders of Interest may include orders for controlled substances, non-controlled substances and/or medical devices.

Suspicious Order – An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

Appropriate Order – An Order of Interest which has been evaluated and determined not to be a Suspicious Order.

Evaluating an Order of Interest

All orders submitted to a Walmart Pharmacy Distribution Center will be monitored and Orders of Interest will be identified and evaluated. All reported Orders of Interest will be evaluated according to the procedures below and the results of the evaluation may be presented to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation to determine whether the Order of Interest is a Suspicious Order. The Health & Wellness Compliance Advisory Panel will provide high level oversight of the evaluation process.

Order of Interest initial inquiries will be conducted by the Pharmacy Logistics Compliance team. The initial inquiry into an Orders of Interest may involve Global Investigations, Practice Compliance, Pharmacy Logistics Compliance, DC associates involved in the monitoring process, and Store/Club associates involved in placing the Order of Interest.

Every Order of Interest will be thoroughly evaluated by the Logistics Compliance team. Orders of Interest, once evaluated and verified as Appropriate, will be processed and shipped as ordered. If an Order of Interest is not resolved within four business days, the Pharmacy Logistics Compliance team will submit documentation related to the outstanding Order of Interest to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation.

The determination of whether an Order of Interest is a Suspicious Order will be made by agreement of the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics. In the event that either party is unavailable, the determination may be made by delegate(s) approved by the Controlled Substance Advisory Panel.

The Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or their delegate(s), will have no longer than two business days to determine if the Order of Interest is an Appropriate or Suspicious Order. If the parties cannot reach an agreement within this time frame, the

Controlled Substance Advisory Panel, or a representative subset of the same, will make the determination.

A store whose order is identified as an Order of Interest and held beyond the expected shipment date will be notified of the shipment delay as quickly as possible.

While each situation requires an individualized approach, below are general guidelines that may be used to evaluate Orders of Interest. Additional guidelines may be available in Pharmacy Logistics and Health & Wellness Practice Compliance procedures.

Initial Inquiry

The Order of Interest should be evaluated to identify the unusual characteristics of the order. Evaluation of the unusual characteristics will assist in making the determination whether or not the Order of Interest is a Suspicious Order.

Unusual characteristics may include:

- Unusual frequency
- Unusual size
- Unusual pattern

Review Prior Orders

The prior order history for the store/club in addition to Item Combinations should be reviewed. This review may include, but should not be limited to the following:

- Whether this store/club has been the subject of an Order of Interest evaluation in the past.
- Overall trending for the item(s) involved in the evaluation.
- Any unusual ordering activity in the past.
- Overall percentages of Controlled Substances relative to other prescription products, and any recent changes.
- Changes to the physical environment of the store/club (for example, a new medical practice opened in their area).
- Changes in drug availability (manufacturer out-of-stock issues).

Interview Store/Club Associates

Associates involved in placing the Order of Interest may be asked to explain the unusual characteristics of the order.

Verify Information Provided by Store/Club Associates

Information provided by store/club associates to explain the unusual characteristics of the order should be verified. For example, if the associate stated that the demand for additional product is a result of a new medical practice in their area, the existence of the practice and the specialty of the new medical practice should be verified.

Documentation and Review

Order of Interest evaluations should be documented using the Order of Interest Evaluation Form.

Suspicious Order Reporting

If it has been determined, after evaluation, that an Order of Interest is a Suspicious Order, the following process will be followed to report the Suspicious Order.

- The Health & Wellness Director of Controlled Substances ("Director") will provide a "Memo of Determination of Suspicious Order" to the following stakeholders:
 - Walmart Health & Wellness Practice Compliance
 - Walmart Health & Wellness Legal
 - Walmart Global Investigations

- Walmart Logistics Compliance
 - Walmart Logistics Legal
 - Walmart Pharmacy Operations
 - Servicing Warehouse General Manager
- The Health & Wellness Director of Controlled Substances will report all Suspicious Orders of controlled substances to the DEA and necessary state agencies, as required by law, within one business day of the determination. The report will be made on the Suspicious Order Regulatory Reporting Form, as approved by Health & Wellness Legal. A remediation plan, if appropriate, may be included in the report. Suspicious Orders of controlled substances that involve suspected criminal activity will additionally be reported to the FDA and the applicable State Board of Pharmacy, as required, within three business days.
 - Suspicious Orders of non-controlled substances and/or medical devices that involve suspected criminal activity will be reported to the FDA and the applicable State Board of Pharmacy, as required, within three business days. The report will be made in the format requested by the applicable agency.

Role of Health & Wellness Director of Controlled Substances and the Health & Wellness Advisory Panel

The Health & Wellness Advisory Panel ("Panel") will be responsible for providing high level oversight of the evaluation process. A summary of all Order of Interest evaluations and all actions taken by the Health & Wellness Director of Controlled Substances ("Director"), including the reports submitted to federal and necessary state agencies will be presented to the Panel by the Director on a routine basis as established by the Panel. The Director, in consultation with the Advisory Panel and Logistics Operations, may provide a remediation plan to the servicing warehouse; field management and pharmacy staffs after Orders of Interest have been evaluated. An Order of Interest evaluation, whether or not determined to be a Suspicious Order may lead to additional oversight of the subject pharmacy. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on specific drugs.

Communication and Documentation Retention

All forms of communication, both internal and external, must be retained. The following guidance should be followed when communicating to ensure proper document retention:

- Telephone and in-person communication should be reduced to written documentation.
- Written communication sent by common carrier must have a delivery confirmation attached to a copy of the document which was sent.
- E-mail and fax communication should be retained electronically along with email or fax confirmation of delivery.

All documentation related to Order of Interest evaluations, determination of Suspicious Orders, and federal and state reporting must be retained for three years.

WMT_MDL_000000966 - WMT_MDL_000000968

21-0402

Pharmacy Manual

Evaluating Orders of Interest and Suspicious Order Reporting



Purpose

DEA, VAWD, and other regulatory agencies require distributors of pharmaceutical products and medical devices to have a system in place designed to identify and report suspicious orders. The following procedure will be followed by Walmart to evaluate Orders of Interest and to report Suspicious Orders to the appropriate federal and state agencies.

Procedures

Definitions

Order of Interest – An order that warrants follow-up evaluation to determine whether it is suspicious. Orders of Interest may include orders for controlled substances, non-controlled substances and/or medical devices.

Suspicious Order – An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

Appropriate Order – An Order of Interest which has been evaluated and determined not to be a Suspicious Order.

Evaluating an Order of Interest

All orders submitted to a Walmart Pharmacy Distribution Center will be monitored and Orders of Interest will be identified and evaluated. All reported Orders of Interest will be evaluated according to the procedures below and the results of the evaluation may be presented to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation to determine whether the Order of Interest is a Suspicious Order. The Health & Wellness Compliance Advisory Panel will provide high level oversight of the evaluation process.

Order of Interest initial inquiries will be conducted by the Pharmacy Logistics Compliance team. The initial inquiry into an Orders of Interest may involve Global Investigations, Practice Compliance, Pharmacy Logistics Compliance, DC associates involved in the monitoring process, and Store/Club associates involved in placing the Order of Interest.

Every Order of Interest will be thoroughly evaluated by the Logistics Compliance team. Orders of Interest, once evaluated and verified as Appropriate, will be processed and shipped as ordered. If an Order of Interest is not resolved within three business days, the Pharmacy Logistics Compliance team will submit documentation related to the outstanding Order of Interest to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation.

The determination of whether an Order of Interest is a Suspicious Order will be made by agreement of the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics. In the event that either party is unavailable, the determination may be made by delegate(s) approved by the Controlled Substance Advisory Panel.

The Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or their delegate(s), will have no longer than three business days to determine if the Order of Interest is an Appropriate or Suspicious Order. If the parties cannot reach an agreement within this time frame, the

Controlled Substance Advisory Panel, or a representative subset of the same, will make the determination.

A store whose order is identified as an Order of Interest and held beyond the expected shipment date will be notified of the shipment delay as quickly as possible.

While each situation requires an individualized approach, below are general guidelines that may be used to evaluate Orders of Interest. Additional guidelines may be available in Pharmacy Logistics and Health & Wellness Practice Compliance procedures.

Initial Inquiry

The Order of Interest should be evaluated to identify the unusual characteristics of the order. Evaluation of the unusual characteristics will assist in making the determination whether or not the Order of Interest is a Suspicious Order.

Unusual characteristics may include:

- Unusual frequency
- Unusual size
- Unusual pattern

Review Prior Orders

The prior order history for the store/club in addition to Item Combinations should be reviewed. This review may include, but should not be limited to the following:

- Whether this store/club has been the subject of an Order of Interest evaluation in the past.
- Overall trending for the item(s) involved in the evaluation.
- Any unusual ordering activity in the past.
- Overall percentages of Controlled Substances relative to other prescription products, and any recent changes.
- Changes to the physical environment of the store/club (for example, a new medical practice opened in their area).
- Changes in drug availability (manufacturer out-of-stock issues).

Interview Store/Club Associates

Associates involved in placing the Order of Interest may be asked to explain the unusual characteristics of the order.

Verify Information Provided by Store/Club Associates

Information provided by store/club associates to explain the unusual characteristics of the order should be verified. For example, if the associate stated that the demand for additional product is a result of a new medical practice in their area, the existence of the practice and the specialty of the new medical practice should be verified.

Documentation and Review

Order of Interest evaluations should be documented using the Order of Interest Evaluation Form.

Suspicious Order Reporting

If it has been determined, after evaluation, that an Order of Interest is a Suspicious Order, the following process will be followed to report the Suspicious Order.

- The Health & Wellness Director of Controlled Substances ("Director") will provide a "Memo of Determination of Suspicious Order" to the following stakeholders:
 - Walmart Health & Wellness Practice Compliance
 - Walmart Health & Wellness Legal
 - Walmart Global Investigations

- Walmart Logistics Compliance
 - Walmart Logistics Legal
 - Walmart Pharmacy Operations
 - Servicing Warehouse General Manager
- The Health & Wellness Director of Controlled Substances will report all Suspicious Orders of controlled substances to the DEA and necessary state agencies, as required by law, within one business day of the determination. The report will be made on the Suspicious Order Regulatory Reporting Form, as approved by Health & Wellness Legal. A remediation plan, if appropriate, may be included in the report. Suspicious Orders of controlled substances that involve suspected criminal activity will additionally be reported to the FDA and the applicable State Board of Pharmacy, as required, within three business days.
- Suspicious Orders of non-controlled substances and/or medical devices that involve suspected criminal activity will be reported to the FDA and the applicable State Board of Pharmacy, as required, within three business days. The report will be made in the format requested by the applicable agency.

Role of Health & Wellness Director of Controlled Substances and the Health & Wellness Advisory Panel

The Health & Wellness Advisory Panel ("Panel") will be responsible for providing high level oversight of the evaluation process. A summary of all Order of Interest evaluations and all actions taken by the Health & Wellness Director of Controlled Substances ("Director"), including the reports submitted to federal and necessary state agencies will be presented to the Panel by the Director on a routine basis as established by the Panel. The Director, in consultation with the Advisory Panel and Logistics Operations, may provide a remediation plan to the servicing warehouse; field management and pharmacy staffs after Orders of Interest have been evaluated. An Order of Interest evaluation, whether or not determined to be a Suspicious Order may lead to additional oversight of the subject pharmacy. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on specific drugs.

Communication and Documentation Retention

All forms of communication, both internal and external, must be retained. The following guidance should be followed when communicating to ensure proper document retention:

- Telephone and in-person communication should be reduced to written documentation.
- Written communication sent by common carrier must have a delivery confirmation attached to a copy of the document which was sent.
- E-mail and fax communication should be retained electronically along with email or fax confirmation of delivery.

All documentation related to Order of Interest evaluations, determination of Suspicious Orders, and federal and state reporting must be retained for three years.

WMT_MDL_000000969 - WMT_MDL_000000971

21-0402

Health and Wellness Manual

Evaluating Orders of Interest and Suspicious Order Reporting



Purpose

The Drug Enforcement Administration, state regulatory agencies and the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributor ("VAWD") accreditation program require distributors of pharmaceutical products and medical devices to have a system in place designed to identify and report suspicious orders. The following procedures will be followed by Walmart to identify and evaluate Orders of Interest and to report Suspicious Orders to appropriate federal and state agencies.

Procedures

Definitions

Order of Interest – An order that warrants follow-up evaluation to determine whether it is suspicious. Orders of Interest may include orders for controlled substances, non-controlled substances and/or medical devices.

Suspicious Order – An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

Appropriate Order – An Order of Interest which has been evaluated and determined not to be a Suspicious Order.

Identifying Controlled Substance Orders of Interest

All controlled substance orders will be processed through the Quintiles IMS Suspicious Order Monitoring application. This application will identify controlled substance Orders of Interest and "pend" (i.e., not ship, and hold for further review) those orders until a follow-up evaluation is completed.

Identifying Non-Controlled Substance Orders of Interest

Non-controlled substance orders of interest will be process through the Reddwerks application. This application will identify non-controlled substance orders of interest and "pend" (i.e., not ship, and hold for further review) those orders until a follow-up evaluation is completed.

Evaluating an Order of Interest

Orders of Interest will be identified and evaluated according to the procedures below. The results of such evaluations may be presented to the Health & Wellness Director of Controlled Substances, the Vice President of Pharmacy Logistics, or a designated representative of each, for further evaluation to determine whether the Order of Interest is a Suspicious Order. The Health & Wellness Compliance Advisory Panel may provide oversight and/or additional advice as needed concerning the evaluation process.

Every Order of Interest will be evaluated by the Pharmacy Logistics Order Monitoring team. The Pharmacy Logistics Order Monitoring Team will conduct an initial evaluation of an Order of Interest. The initial inquiry into an Order of Interest may involve communications with Pharmacy associates that were involved in placing the Order of Interest.

Orders of Interest once evaluated and determined to be Appropriate Orders, will be processed and shipped as ordered. If an Order of Interest is not resolved within three business days, the Pharmacy Logistics Order Monitoring team will submit documentation related to the outstanding Order of Interest to

the Health & Wellness Director of Controlled Substances and the Vice President of Pharmacy Logistics, or a designated representative of each, for further evaluation.

The determination of whether an Order of Interest is a Suspicious Order may be made after review by the Health & Wellness Director of Controlled Substances and the Vice President of Pharmacy Logistics. In the event that either party is unavailable, the determination may be made by delegate(s) approved by the Controlled Substance Advisory Panel.

The Health & Wellness Director of Controlled Substances and the Vice President of Pharmacy Logistics, or their delegate(s) will determine if the Order of Interest is an Appropriate or Suspicious Order no later than six business days from the order date. If a determination cannot be made within this time frame, the Controlled Substance Advisory Panel, or a panel of at least three members of the Controlled Substance Advisory Panel, will make the determination.

A Pharmacy whose order is identified as an Order of Interest and held beyond the expected shipment date will be notified of the shipment delay as quickly as possible.

While each situation requires an individualized approach based on the facts and circumstances, below are general guidelines that may be used to evaluate Orders of Interest. Additional guidelines may be available in Pharmacy Logistics and Health & Wellness Practice Compliance procedures.

Initial Inquiry

The Order of Interest should be evaluated to identify the characteristics of the order. Evaluation of the characteristics will assist in making the determination whether or not the Order of Interest is a Suspicious Order.

Unusual characteristics may include:

- Unusual frequency
- Unusual size
- Unusual pattern

Review Prior Orders

The prior order history and ordering pattern for the Pharmacy may be reviewed. This review may include the following:

- Whether this Pharmacy has been the subject of an Order of Interest evaluation in the past.
- Overall trending for the item(s) involved in the evaluation.
- Overall percentages of controlled substances relative to other prescription products, and any recent changes.
- Changes to the demographics/surrounding areas of the Pharmacy (for example, a new medical practice opened in their area).
- Changes in drug availability (manufacturer out-of-stock issues).

Interview Pharmacy Associates

Associates involved in placing the Order of Interest may be asked to explain the characteristics of the order.

Verify Information Provided by Pharmacy Associates

Information provided by Pharmacy associates to explain the characteristics of the Order of Interest should be verified. For example, if the associate states that the demand for additional product is a result of a new medical practice in their area, the existence of the practice and the specialty of the new medical practice should be verified.

Documentation and Review

Order of Interest evaluations should be documented in Archer using the Suspicious Order Monitoring Incident form.

Suspicious Order Reporting

If it has been determined, after evaluation, that an Order of Interest is a Suspicious Order, the following process will be followed to report the Suspicious Order.

- The Health & Wellness Director of Controlled Substances will provide a notification of determination of suspicious order to the relevant stakeholders.
- The Health & Wellness Director of Controlled Substances will report all Suspicious Orders of controlled substances to the DEA and state agencies, as required by law, within one business day of the determination. Suspicious Orders of controlled substances that involve suspected criminal activity may also be reported to the FDA and the applicable State Board of Pharmacy, as required, within three business days.
- Suspicious Orders of non-controlled substances and/or medical devices that involve suspected criminal activity will be reported to the FDA and the applicable State Board of Pharmacy, as required by law, within three business days. The report will be made in the format requested by the applicable agency.

Additional Oversight

The Health & Wellness Director of Controlled Substances may provide a remediation plan to the servicing warehouse, field management and pharmacy staffs after Orders of Interest have been evaluated. An Order of Interest evaluation, whether or not determined to be a Suspicious Order may lead to additional oversight of the subject pharmacy. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on specific drugs.

Communication and Documentation Retention

All forms of communication, both internal and external, must be retained. The following guidance should be followed when communicating to ensure proper document retention:

- Telephone and in-person communication should be reduced to written documentation if practicable.
- Written communication sent by common carrier must have a delivery confirmation attached to a copy of the document which was sent.
- E-mail and fax communication should be retained electronically along with email or fax confirmation of delivery.

All documentation related to Order of Interest evaluations, determination of Suspicious Orders, and federal and state reporting must be retained for three years.

WMT_MDL_000004237 - WMT_MDL_000004239



Controlled Substances Suspicious Order Monitoring

Purpose

DEA regulations require distributors of controlled substances to have a system in place designed to identify suspicious orders of controlled substances. This guidance document will outline the role of Practice Compliance in evaluating orders of interest and reporting suspicious orders to the appropriate federal and state agencies.

Definitions

Order of Interest: An order that warrants follow-up evaluation to determine whether it is suspicious.

Suspicious Order: An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

Appropriate Order: An Order of Interest which has been evaluated and determined not to be a Suspicious Order.

Procedures

Initial Evaluation

All controlled substance orders submitted to a Walmart pharmacy distribution center will be monitored and Orders of Interest will be identified. Order of Interest initial evaluations will be conducted by the Pharmacy Logistics Compliance team in accordance with Pharmacy Manual 21-402 (Logistics) and Pharmacy Logistics Procedures. At a high level, the following steps may be taken to evaluate an Order of Interest:

- Determine the unusual characteristics of the order
- Review prior order history
- Interview store/club associates
- Verify information provided by store/club associates
- Review any prior concerns regarding the pharmacy in question (if applicable)

Additional Evaluation

If an Order of Interest is not resolved within 3 business days or if the Pharmacy Logistics Compliance team determines that an additional evaluation is needed, the Director of Controlled Substances ("Director") will perform an additional evaluation. The additional evaluation shall include, at a minimum, a review of all notes from the Pharmacy Logistics Compliance team's evaluation. The



Controlled Substances Suspicious Order Monitoring

Director or Sr. Director of Pharmacy Logistics ("Sr. Director") may request additional information to aid in their determination if an Order of Interest is a Suspicious Order.

Determination

The determination of whether the Order of Interest is a Suspicious Order will be made by agreement of the Director and the Sr. Director. In the event either the Director or Sr. Director is unavailable, the determination may be made by delegate(s) approved by the Controlled Substance Advisory Panel ("Panel").

The Director and Sr. Director will have no longer than 3 business days to determine if the Order of Interest is an Appropriate or Suspicious Order. If an agreement cannot be reached between the Director and Sr. Director, the Panel (or a representative subset of the Panel) will make the determination.

If the Order of Interest is determined to be appropriate, Pharmacy Logistics will be notified that they may ship the order. If the Order of Interest is determined to be a Suspicious Order, the Director will be responsible for reporting the Suspicious Order to key stakeholders, the Drug Enforcement Agency (DEA) and state agencies as required by law.

Suspicious Order Reporting

The Director will report the Suspicious Order of a controlled substance as outlined in Pharmacy Manual 21-402: Evaluating Orders of Interest and Suspicious Order Reporting.

Documentation

The Director will document the final conclusion of the evaluation. The Director will also retain documentation of any reports made to the DEA and state agencies

Remediation

The Director will develop an appropriate remediation plan for suspicious orders that may include one or more of the following elements:

- Engaging Global Investigations to open a review of the ordering facility.
- Requiring an on-site visit by Health & Wellness Operations to conduct a review and additional training at the facility.
- Increased oversight of all orders from the facility for a period of time.
- Reduction in the amount of product shipped for a period of time.
 - Due to limitations in the replenishment system, the distribution center may be required to "cut" the store's order to limit the product they receive until the replenishment system recognizes the new lower demand from the facility.
 - These cuts will show a reason code of "SOM Remediation"



Controlled Substances Suspicious Order Monitoring

Oversight

The following oversight activities will be conducted to help ensure the effectiveness of the Suspicious Order Monitoring Program:

- Director will periodically conduct a post-determination review of Order of Interest evaluations conducted by the Pharmacy Logistics Compliance team including all evaluation notes.
- Director and Pharmacy Logistics Compliance will periodically review order thresholds and make recommendations for threshold adjustments. Threshold adjustments must be approved by both the Director and Sr. Director and documented.
- Director will present a summary report of Order of Interest evaluations to the Panel on a periodic basis.
- Director may make recommendations to the Panel for additional oversight of certain pharmacies. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on the order of specific drugs.

WMT_MDL_000004781 - WMT_MDL_000004783



Controlled Substances Suspicious Order Monitoring

Purpose

DEA regulations require distributors of controlled substances to have a system in place designed to identify suspicious orders of controlled substances. This guidance document will outline the role of Practice Compliance in evaluating orders of interest and reporting suspicious orders to the appropriate federal and state agencies.

Definitions

Order of Interest: An order that warrants follow-up evaluation to determine whether it is suspicious.

Suspicious Order: An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders ~~may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency pursuant to 21 C.F.R. 1301.74(b)~~ include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Appropriate Order: An Order of Interest which has been evaluated and determined not to be a Suspicious Order.

Procedures

Initial Evaluation

All controlled substance orders submitted to a Walmart pharmacy distribution center will be monitored and Orders of Interest will be identified. Order of Interest initial evaluations will be conducted by the Pharmacy Logistics ~~Compliance Order Monitoring~~ team in accordance with Pharmacy Manual 21-402 (Logistics) and Pharmacy Logistics Procedures. At a high level, the following steps may be taken to evaluate an Order of Interest:

- ~~Determine~~ Review the unusual characteristics of the order
- Review prior order history
- Interview ~~store/club~~ pharmacy associates
- Verify information provided by ~~store/club~~ pharmacy associates
- Review any prior concerns regarding the pharmacy in question (if applicable)

Additional Evaluation

If an Order of Interest is not resolved within 3 business days or if the Pharmacy Logistics ~~Compliance Order Monitoring~~ team determines that an additional evaluation is needed, the Director of Controlled Substances ("Director") will perform an additional evaluation. The additional evaluation ~~shall~~



Controlled Substances Suspicious Order Monitoring

may include, ~~at a minimum,~~ a review of all notes from the Pharmacy Logistics ~~Compliance Order~~ Monitoring team's evaluation. The Director or Sr. Director of Pharmacy Logistics ("Sr. Director") may request additional information to aid in their determination ~~if of whether~~ an Order of Interest is a Suspicious Order.

Determination

The determination of whether the Order of Interest is a Suspicious Order will be made by agreement of the Director and the Sr. Director. In the event either the Director or Sr. Director is unavailable, the determination may be made by delegate(s) approved by the Controlled Substance Advisory Panel ("Panel").

The Director and Sr. Director ~~will have no longer than 3 business days to~~ should determine if the Order of Interest is an Appropriate Order or a Suspicious Order no later than 6 business days from the order date. If an agreement cannot be reached between the Director and Sr. Director, the Panel (or a representative subset of the Panel) will make the determination.

If the Order of Interest is determined to be appropriate, Pharmacy Logistics will be notified that they may ship the order. If the Order of Interest is determined to be a Suspicious Order, the Director will be responsible for reporting the Suspicious Order to key stakeholders, the Drug Enforcement Agency (DEA) and state agencies as required by law.

Suspicious Order Reporting

The Director will report the Suspicious Order of a controlled substance as outlined in Pharmacy Manual 21-402: Evaluating Orders of Interest and Suspicious Order Reporting.

Documentation

The Director will document the ~~final~~ conclusion of the order evaluation. The Director will also retain ~~documentation of~~ any reports made to the DEA and state agencies.

Remediation

The Director will develop an appropriate remediation plan for suspicious orders that may include one or more of the following elements:

- Engaging Global Investigations to open a review of the ordering facility.
- Requiring an on-site visit by Health & Wellness Operations to conduct a review and additional training at the facility.
- Increased oversight of all orders from the facility for a period of time.
- Reduction in the amount of product shipped for a period of time.



Controlled Substances Suspicious Order Monitoring

- Due to limitations in the replenishment system, ~~the distribution center may be required to "cut" the store's order~~ orders may be "cut" to limit the product ~~a facility they~~ receives until the replenishment system recognizes the new lower demand from the facility.
- ~~These cuts will show a reason code of "SOM Remediation"~~

Oversight

The following oversight activities ~~will~~ may be conducted to help ensure the effectiveness of the Suspicious Order Monitoring Program:

- Director ~~will~~ may periodically conduct a post-determination review of Order of Interest evaluations conducted by the Pharmacy Logistics Compliance team including all evaluation notes.
- ~~Director and Pharmacy Logistics Compliance will periodically review order thresholds and make recommendations for threshold adjustments. Threshold adjustments must be approved by both the Director and Sr. Director and documented.~~
- Director ~~will~~ may present a summary report of Order of Interest evaluations to the Panel on a periodic basis.
- ~~Director may make recommendations to the Panel for additional oversight of certain pharmacies. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on the order of specific drugs.~~

WMT_MDL_000008377 - WMT_MDL_000008379



Controlled Substances Suspicious Order Monitoring

Purpose

DEA regulations require distributors of controlled substances to have a system in place designed to identify suspicious orders of controlled substances. This guidance document will outline the role of Practice Compliance in evaluating orders of interest and reporting suspicious orders to the appropriate federal and state agencies.

Definitions

Order of Interest: An order that warrants follow-up evaluation to determine whether it is suspicious

Suspicious Order: An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

Procedures

Initial Evaluation

All controlled substance orders submitted to a Walmart pharmacy distribution center will be monitored and Orders of Interest will be identified. Order of Interest initial evaluations will be conducted by the Pharmacy Logistics Compliance team in accordance with Pharmacy Manual XX-XXX (Logistics) and Pharmacy Logistics Procedures. At a high level, the following steps may be taken to evaluate an Order of Interest:

- Determine the unusual characteristics of the order
- Review prior order history
- Interview store/club associates
- Verify information provided by store/club associates
- Review any prior concerns regarding the pharmacy in question (if applicable)

Additional Evaluation

If an Order of Interest is not resolved within 4 business days or if the Pharmacy Logistics Compliance team determines that an additional evaluation is needed, the Director of Controlled Substances ("Director") will perform an additional evaluation. The determination of whether the Order of Interest is a Suspicious Order will be made by agreement of the Director and the Sr. Director of Pharmacy Logistics ("Sr. Director"). The additional evaluation shall include, at a minimum, a review of all notes from the Pharmacy Logistics Compliance team's evaluation. The Director or Sr. Director may request additional information to aid in their determination if an Order of Interest is a Suspicious Order.



Controlled Substances Suspicious Order Monitoring

Determination

The Director and Sr. Director will have no longer than 2 business days to determine if the Order of Interest is appropriate or is a Suspicious Order.

If the Order of Interest is determined to be appropriate, Pharmacy Logistics will be notified that they may ship the order. If the Order of Interest is determined to be a Suspicious Order, the Director will be responsible for reporting the Suspicious Order to key stakeholders, the Drug Enforcement Agency (DEA) and state agencies as required by law.

Suspicious Order Reporting

The Director will report the Suspicious Order to DEA and state agencies (as required) when discovered. The report will be made on the Suspicious Order Regulatory Reporting Form, as approved by Health & Wellness Legal.

Documentation

The Director will document the final conclusion of the evaluation, including why the order was determined to be appropriate or suspicious. The Director will also retain notes and documentation of any reports made to the DEA and state agencies

Oversight

The following oversight activities will be conducted to ensure the effectiveness of the Suspicious Order Monitoring Program:

- Director will conduct a post-determination review of all Order of Interest evaluations conducted by the Pharmacy Logistics Compliance team including, if applicable, all evaluation notes.
- Director will present a summary report of Order of Interest evaluations to the Controlled Substance Advisory Panel ("Panel") on a regular basis.
- Director will periodically compare the Order of Interest thresholds with DEA 106 filings and make recommendations of threshold adjustments due to theft or significant loss in the subject pharmacy. Threshold adjustments must be approved by both the Director and Sr. Director and documented.
- Director may make recommendations to the Panel for additional oversight of certain pharmacies due to a Suspicious Order or an Order of Interest that was determined not to be suspicious. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on the order of specific drugs.



Controlled Substances Suspicious Order Monitoring

Resources

- Suspicious Order Reporting Regulatory Form
- State Reporting Requirements

WMT_MDL_000011106

21- 402

Pharmacy Manual

Controlled Substance Monitoring



Purpose

To provide guidelines for monitoring controlled substance purchases at the Pharmacy Distribution Center (DC).

Resources

Link	Resources
Reports	
SD405-1	Control Drug Stock Exception Report by Item
SD405-2	Control Drug Stock Exception Report by Store

Procedures

Identifying and Reporting Purchases of Controlled Substances

Pharmacy Asset Protection (AP) Managers

By the fifth day of each month, the Pharmacy AP manager retrieves the SD405-1 and SD 405-2 from Document Direct. Upon retrieval, the AP manager analyzes each report for the following:

- **SD405-1**
 - The Percent to Total column, which displays for any entry over 3.99%
 - Any entry with a Percent to Total over 3.99% appears on a separate spreadsheet along with the store number, item number, and item name.
 - The Excel document used to maintain those stores identified will be sent by electronic email to the Sr. AP Manager of Pharmacy Logistics.
- **SD405-2**
 - The Percent to Total column must be reviewed for any entry above 3.99%
 - Identify any entries with a Percent to Total above 3.99% on a separate document and include the store number, item number, and item name.
 - Email the document used to maintain the identified stores to the senior AP manager of Pharmacy Logistics.

Senior AP Manager Pharmacy Duties

Upon the receipt of the Excel document indicating those stores and items above the 3.99% threshold, the Sr. AP Pharmacy Manager will forward the reports to the appropriate Drug Diversion Coordinator for further review.

Document Retention

All Excel documents and electronic email documents pertaining to this reporting procedure will be kept on file for 3 years.

WMT_MDL_000011107 - WMT_MDL_000011109

21-402

Pharmacy Manual

Evaluating Orders of Interest and Suspicious Order Reporting



Purpose

DEA regulations require distributors of controlled substances to have a system in place designed to identify suspicious orders. The following procedure will be followed by Walmart to evaluate Orders of Interest and to report Suspicious Orders to the appropriate federal and state agencies.

Definitions

Order of Interest – An order that warrants follow-up evaluation to determine whether it is suspicious.

Suspicious Order – An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

Appropriate Order – An Order of Interest which has been evaluated and determined not to be a Suspicious Order.

Procedures

Evaluating an Order of Interest

All drug orders submitted to a Walmart Pharmacy Distribution Center will be monitored and Orders of Interest will be identified and evaluated. All reported Orders of Interest will be evaluated according to the procedures below and the results of the evaluation may be presented to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation to determine whether the Order of Interest is a Suspicious Order. The Health & Wellness Compliance Advisory Panel will provide high level oversight of the evaluation process.

Order of Interest initial inquiries will be conducted by the Pharmacy Logistics Compliance team. The initial inquiry into an Orders of Interest may involve Global Investigations, Practice Compliance, Pharmacy Logistics Compliance, DC associates involved in the monitoring process, and Store/Club associates involved in placing the Order of Interest.

Every Order of Interest will be thoroughly evaluated by the Logistics Compliance team. Orders of Interest, once evaluated and verified as appropriate, will be processed and shipped as ordered. If an Order of Interest is not resolved within 4 business days, the Pharmacy Logistics Compliance team will submit documentation related to the outstanding Order of Interest to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation.

The determination of whether an Order of Interest is a Suspicious Order will be made by agreement of the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics. In the event that either party is unavailable, the determination may be made by delegate(s) approved by the Controlled Substance Advisory Panel.

The Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or their delegate(s), will have no longer than two business days to determine if the Order of Interest is an Appropriate or Suspicious Order. If the parties cannot reach an agreement within this time frame, the Controlled Substance Advisory Panel, or a representative subset of the same, will make the determination.

A store whose order is identified as an Order of Interest and held beyond the expected shipment date will be notified of the shipment delay as quickly as possible.

While each situation requires an individualized approach, below are general guidelines that may be used to evaluate Orders of Interest. Additional guidelines may be available in Pharmacy Logistics and Health & Wellness Practice Compliance procedures.

Initial Inquiry

The Order of Interest should be evaluated to identify the unusual characteristics of the order. Evaluation of the unusual characteristics will assist in making the determination whether or not the Order of Interest is a Suspicious Order.

Unusual characteristics may include:

- Unusual frequency
- Unusual size
- Unusual pattern

Review Prior Orders

The prior order history for the store/club in addition to Item Combinations should be reviewed. This review may include, but should not be limited to the following:

- Whether this store/club has been the subject of an Order of Interest evaluation in the past.
- Overall trending for the item(s) involved in the evaluation.
- Any unusual ordering activity in the past.
- Overall percentages of Controlled Substances relative to other prescription products, and any recent changes.
- Changes to the physical environment of the store/club, such as a new medical practice opened in their area.
- Changes in drug availability. (Manufacturer out-of-stock issues.)

Interview Store/Club Associates

Associates involved in placing the Order of Interest may be asked to explain the unusual characteristics of the order.

Verify Information Provided by Store/Club Associates

Information provided by store/club associates to explain the unusual characteristics of the order should be verified. For example, if the associate stated that the demand for additional product is a result of a new medical practice in their area, the existence of the practice and the specialty of the new medical practice should be verified.

Documentation and Review

All Order of Interest evaluations must be documented.

Suspicious Order Reporting

If it has been determined, after evaluation, that an Order of Interest is a Suspicious Order, the following process will be followed to report the Suspicious Order to key stakeholders, to the Drug Enforcement Administration (DEA) and necessary state agencies, as required by law.

- The Health & Wellness Director of Controlled Substances ("Director") will provide a "Memo of Determination of Suspicious Order" to the following stakeholders:
 - Walmart Health & Wellness Practice Compliance
 - Walmart Health & Wellness Legal
 - Walmart Global Investigations
 - Walmart Logistics Compliance
 - Walmart Logistics Legal

- Walmart Pharmacy Operations
- Servicing Warehouse General Manager
- The Health & Wellness Director of Controlled will report all Suspicious Orders to the DEA and necessary state agencies, as required by law, within one business day of the determination. The report will be made on the Suspicious Order Regulatory Reporting Form, as approved by Health & Wellness Legal. A remediation plan, if appropriate, may be included in the report.

Role of Health & Wellness Director of Controlled Substances and the Health & Wellness Advisory Panel

The Health & Wellness Advisory Panel ("Panel") will be responsible for providing high level oversight of the evaluation process. A summary of all Order of Interest evaluations and all actions taken by the Health & Wellness Director of Controlled Substances ("Director"), including the reports submitted to federal and necessary state agencies will be presented to the Panel by the Director on a routine basis as established by the Panel. The Director, in consultation with the Advisory Panel and Logistics Operations, may provide a remediation plan to the servicing warehouse; field management and pharmacy staffs after Orders of Interest have been evaluated. An Order of Interest evaluation, whether or not determined to be a Suspicious Order may lead to additional oversight of the subject pharmacy. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on specific drugs.

Communication and Documentation Retention

All forms of communication, both internal and external, must be retained. The following guidance should be followed when communicating to ensure proper document retention:

- Telephone and in-person communication should be reduced to written documentation.
- Written communication sent by common carrier must have a delivery confirmation attached to a copy of the document which was sent.
- E-mail and fax communication should be retained electronically along with email or fax confirmation of delivery.

All documentation related to Order of Interest evaluations, determination of Suspicious Orders, and federal and state reporting must be retained for three years.